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Bcc:
Subject: ADCS Sprinkle study
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[REDACTED]

Got your voice mail on the preliminary results of the ADCS Depakote Sprinkle Study.
Thanks for the update. It is unfortunate the results were not as robust as hoped.

Just some reminders -- With an of N=150, I do not believe that this was a highly powered study to begin with in light of the endpoints used (BPRS as primary and CMAI as secondary, I think). Abbott estimated a need for 396 patients to detect statistically significant difference on the CMAI (80% power) with Depakote compared to placebo in a similar population in our trial, M99-082. I could be wrong about the power on the Sprinkle study, but that is perhaps one issue to ask about. If that is the case, even if a "trend" for Depakote is shown, that could be seen as favorable data--especially if the safety data looks good.

Also, with what we know now, the 750mg dose is probably a bit too low to really give Depakote the best chance. We find that for behavioral symptom control in patients with active symptoms, most need about 15 mg/kg/day (or at least around 1000mg if an average fixed dose is to be used)- - just a bit more than was prescribed in this trial.

This is a federally funded trial through the ADCS, and though we contributed some monies, it is not our study. So, I am not sure if we will be privy to any subanalyses, or what types they consider. (?)

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